Original Research Article

Diagnostic efficiency of vibratip in detecting diabetic peripheral neuropathy

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Abstract

Background: The incidence and prevalence of type 2 diabetes mellitus is increasing worldwide, due to the sedentary life style pattern, unhealthy food habits and stressful life. The complications of diabetes are also increasing in par with the incidence and prevalence. Various complications incurred by diabetics are confined to vascular system and nervous system. Sensory symptoms predominate in majority of cases. Sensory neuropathy leads to repeated tissue injury, which may lead to foot ulcer and amputation. To decrease the morbidity rate, early detection of sensory neuropathy is essential. The tests to identify the loss of protective sensation are numerous and ill defined. The aim of this study is to find the diagnostic efficiency of vibratip in detecting diabetic peripheral neuropathy. **Materials and Methods:** This study is a case control study, with 50 type 2 diabetes mellitus patients and 50 age and sex matched controls. Patients were from Annapoorana Medical college hospitals. Ethical clearance was got from ethical committee of Annapoorana medical college. Informed consent was got from patients. The tests done were Vibration perception threshold by sensitometer and vibration perception by vibratip. **Results:** The measure of agreement between sensitometer and vibratip done by kappa test was 0.593 and 0.672. P value is significant 0.0005. The measure of association between sensitometer and vibratip was done by Mcnemer's test, which was 1.000, which means both were equally efficient tests for testing vibration sensation. Sensitivity, specificity, positive and negative predictive values were found out for both the tests. For sensitometer it was found to be 82%,90%, 89% and 83% respectively. For vibratip the sensitivity was 82%, specificity was 82%, positive predictive value was 82% and negative predictive value was 82%. **Conclusion:** Our test results conclude that vibration sensation testing by vibratip is equally efficient to sensitometer and could be a useful screening tool for peripheral neuropathy.
Key Words: Type 2 diabetes mellitus, neuropathy, Vibration perception test, Vibratip.

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INTRODUCTION

The prevalence of Type 2 diabetes mellitus is emerging as a global epidemic. Diabetic Peripheral Neuropathy, which is the most important complication of diabetes is becoming widespread. Distal symmetrical neuropathyis most common and accounts for 75% of diabetic peripheral neuropathy (DPN)[1]. For every 30 seconds a lower limb is lost somewhere in the world as a result of diabetes. This increases the mortality rate also. Long-term complications of diabetes, like foot ulceration and amputation, causes 5% of National Health Care expenditure [2] Various studies suggest that the rate of lower limb amputation can be reduced by simple and improved screening procedures[3]. Vibration perception threshold (VPT) is one of the simple way of detecting, large-fiber dysfunction and thus identifying the diabetic population at risk of ulceration[4,5].Vibration Perception threshold (VPT) can be assessed by various instruments like Biothesiometer, Neurothesio meter, Maxvibrometer and Vibrameter. The size and cost of these instruments seems to be a limitation for their use. Diagnosis of peripheral neuropathy by sensitometer is time consuming and its usage needs expertisation in handling the instrument. So this cannot be used for diagnosing diabetic peripheral neuropathy on a large size of population. The vibratip is a novel device which produces a constant vibratory stimulus and therefore

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assesses vibration sense. This study evaluated the diagnostic efficiency of the vibratip compared to sensitometer and whether vibratip could be used as a simple test for detecting diabetic peripheral neuropathy.

MATERIALS AND METHODS

This is a case control study with 100 subjects. 50 Patients in the age group of 30 to 70 years with established type 2 diabetes (WHO criteria) [6] with duration more than 3 years from Annapoorana medical college and hospital were recruited. Fifty age, height and sex matched healthy subjects were included in the control group. Informed consent was taken from all subjects. Inclusion criteria for: Cases included:- Age between 30-70years, Type 2 diabetes mellitus ,Controls included Healthy subjects with Fasting blood sugar < 100mg/dl. Exclusion criteria for cases and control were :- Those with symptoms related to other neuropathies, Chronic renal failure, Previous spinal injury, History of cervical or lumbar discopathies, History of vitamin B12 or folate deficiency, History of alcohol abuse, Skin diseases (neurodermatitis, psoriasis, scleroderma, allergy to metals, Raynaud syndrome, hyperhidrosis, or acrocyanosis). All the cases and controls were subjected to vibration perception threshold by sensitometer and vibratip. Vibration perception threshold was tested using Sensitometer, Dhansai laboratory, Mumbai. After explaining the procedure, the probe was applied to great toe, first metatarsal, third metatarsal, fifth metatarsal, middle arch, heel, dorsal pedis, posterior tibial arch of both the feet with the patient in supine position in a quiet room. The vibration was increased gradually from minimum voltage and transition from no vibration to the onset of perceiving vibration was taken as vibration perception threshold. The Yes/No method was used. vibration perception threshold was tested on eight areas on foot. An average of all the values was taken as vibration perception threshold. The vibration perception threshold was measured in millivolts. A voltage more than 25 mV was taken as presence of neuropathy. The vibratip (McCallan Medical,Nottingham,UK) is a new disposable device that provides a near -silent vibration using a vibrating motor powered by a mercury and lithium free button cell in a clean sealed disposable unit, with specified amplitude and frequency similar to but more consistent than that of a 128 Hz calibrated tuning fork , that has been developed in order to screen for diabetic peripheral neuropathy. Vibration stimulus from vibratip is less affected by local skin conditions such as callus. Vibratip was held gently between thumb and index finger. The vibratip was tested briefly by pressing the activation button to confirm the vibration of the device. The vibratip was applied to the patient's hallux with the patient's eyes closed, once when non vibrating and once when vibrating and the patients were asked to respond when they feel the vibration. If the patients were unable to detect the vibrations, the presence of diabetic peripheral neuropathy was suggested and the we have to investigate further. The rounded tip of the vibratip was cleaned with alcohol swab between uses.

Statistical analysis was done using SPSS 16. Kappa test and Mcnemar test were the tests done for finding the efficiency of vibratip compared to sensitometer in detecting diabetic peripheral neuropathy.

Ethical approval: This study was approved by the Institutional Ethics Committee.

OBSERVATION AND RESULTS

The measure of agreement between sensitometer and vibratip was found out by kappa test which was found to be 0.593 and 0.672 respectively. K value normally falls between -1 and +1. Our value of 0.593 and 0.672 falls on the positive side. There is moderate agreement between the two tests. The P value is 0.0005. The two tailed Mcnemer's chi square test result was significant with the value1.000.The demography of patients assessed for peripheral neuropathy with sensitometer and vibratip is given in Table 1.Kappa test results were given in table 2 The sensitivity, specificity, positive predictive value and negative predictive value of sensitometer and vibratip were shown in Table3.Interpretation of degree of diagnostic reliability was based on the standard scale of Landis and Koch (1977),< 0 –No agreement, 0-0.20---slight, 0.21—0.40---Fair, 0.41-0.60-- Moderate, 0.61-0.80---substantial, 0.81-1.0---perfect [7].

Table 1: Demography of patients assessed for peripheral neuropathy with sensitometer and vibratip

Parameters	Mean and range
Age	Mean= 48. Range =30-70 years
Gender	Male = 25
	Female=25
BMI	Mean=25.Range=20-30
Fasting blood glucose level	Mean=137.Range=110-176mg
Duration of diabetes	Mean=7.Range=4-12 years.

Table 2: Measure of Agreement by kappa test

Tests	values	significance
Vpt by sensitometer	.593	.000
Vibration perception by vibratip	.672	.000

Table 3: The sensitivity, specificity ,positive predictive value and negative predictive value of sensitometer and vibratip

	Sensitometer	vibratip
Sensitivity	82%	82%
Specificity	90%	82%
Positive predictive value	89%	82%
Negative predictive value	83%	82%

DISCUSSIONS

Diabetic peripheral neuropathy results from high blood sugar levels causing nerve damage. Symptoms include numbness, tingling and pain in the feet and hands, muscle weakness and foot ulcers. The chances of developing serious complications is reduced by early diagnosis and reduction or delay in nerve damage can be made possible by strict blood sugar control. The clinical features of large fibre neuropathy are, impaired vibration, loss of joint, position sense, weakness, wasting. The clinical features of small fibre neuropathy are pain and thermal sensations and autonomic functions. The first modality of sensation to be lost in the development of diabetic peripheral neuropathy is vibration sensation. Diagnosing the loss of vibration perception sensation in the earlier stage itself, will reduce the incidence of foot ulcers and amputation, which will reduce the morbidity and mortality. Many instruments like Biothesiometer, Neurothesio meter, Maxvibrometer and Vibrameter are there for assessing the vibration perception.The size of the instruments and the expertisation needed for their operation is the reason for the limitation of their use as a screening tool in a group of population. Our study assess the diagnostic efficiency of vibratip compared to sensitometer. The reason why we want to assess the efficiency of vibratip in diagnosing Diabetic peripheral Neuropathy is 1.It is a portable instrument,2.Cost effective,3. It uses vibration rather than pressure, thereby providing a stimulus that remains constant between patients.4.It offers continuous operation over its battery life.5.No training needed for operating vibratip. Levy *et al.*, from their study on Preliminary data on vibratip, a new source of standardized vibration for bed side assessment of peripheral neuropathy, demonstrated that, vibratip was more effective in detecting neuropathy than 128 Hz tuning fork and 10 g monofilament [8]. Hisham Nizar *et al.* in their study concluded that vibratip is comparable to the neurothesiometer, and superior to the tuning fork, in the detection of peripheral neuropathy and could be used as a screening tool in clinical practice [9]. N. Bracewell *et al.*, concluded that the device vibratip is comparable with the 10-g monofilament and could be considered a useful tool for screening for peripheral sensory neuropathy in diabetes [10]. The NICE Committee concluded that vibratip is a promising technology with the potential to have a positive impact on the diagnosis of diabetic peripheral neuropathy[11]. The measure of agreement between sensitometer and vibratip was found out by kappa test which was found to be 0.593 and 0.672 respectively, shows the moderate agreement between the two tests. The P value is 0.0005, which shows that vibratip can be used in the place of sensitometer. The two tailed Mcnemer's chi square test result was significant with the value 1.000. So both sensitometer and vibratip are equally efficient and vibratip can be used in the place of sensitometer. Since the sensitivity of sensitometer and vibratip were 82 %, the efficiency of vibratip in disgnosing peripheral neuropathy is equal to that of sensitometer. Our study compared the efficiency of vibratip in detecting Diabetic peripheral Neuropathy with that of sensitometer. We found that Both are equally efficient and vibratip can be used as a simple tool for detecting diabetic peripheral neuropathy.

CONCLUSION

From our study we come to a conclusion that the vibratip is a reliable and efficient tool for detecting the peripheral neuropathy. Since vibration perception is the first sensation to get affected in Diabetic Peripheral Neuropathy [12], all diabetic patients should be assessed for vibration perception, irrespective of the clinical symptoms. The rate of re-ulceration is decreased by 60% and lower extremity amputation by 85 % by early detection of diabetic peripheral neuropathy[13,16].For early detection of Diabetic Peripheral Neuropathy routine screening should be carried out at least once in a year, and if they had foot ulcer before the foot examination should be done in every 3 to 6 months. months. This will prevent the long term complication of foot ulcer, amputation, reduce the morbidity. Vibration perception tested with Vibratip used in this study is an inexpensive, and reliable method, can be used by health care personals, So Vibratip can be included in future algorithms for diabetic foot examination, and can be used as an efficient tool for detecting diabetic peripheral neuropathy in a larger population.

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